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GORE ENTERPRISE HOLDINGS, INC. 551 PAPER MILL ROAD P. O. BOX 9206 NEWARK, DE 19714-9206			MENDEZ, MANUEL A	
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/384,900
Filing Date: August 27, 1999
Appellant(s): LAGUNA ET AL.

MAILED

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SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to the reply brief filed on April 13, 2005.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 24-42 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by **Daneshvar (US 5,728,066)**. Daneshvar teaches a balloon that is slidable along a catheter (col. 3, lines 21-25). Daneshvar further teaches that the balloon does not leak between itself and the catheter that it is mounted on. (col. 9, lines 40-45).

Claims 24, 25, 29, 32-34, 37, and 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by **Kraus, et al., (US 5,718,680)**. Kraus teaches all the claimed subject matter including the balloon being attached to a non-distensible member (inner tube 21) to render the ends non-distensible, and that it can be made from polytetrafluoroethylene (PTFE); (col. 7, para 1).

Claims 28, 30, 31, 36, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Daneshvar in view of Crocker, et al., (US 5,843,116)**. This rejection is set forth in a prior Office Action, mailed on September 8, 2003.

Claims 27 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Daneshvar in view of Ravenscroft, et al., (US 5,766,201)**. This rejection is set forth in a prior Office Action, mailed on September 8, 2003.

(11) Response to Argument

The examiner of record acknowledges appellant's request that the grounds for rejection be considered against independent claim 24 alone. Accordingly, for the purposes of this appeal, claims 23-42 will stand or fall together with independent claim 24.

ANALYSIS

In relation to claim 24, the Appellant argues that the present invention as claimed differs from the prior art because the balloon sleeve of the present invention is rendered non-distensible prior to being formed into a balloon by mounting on the catheter shaft.

Claim 24 defines the present invention as follows:

A sleeve adapted to be mounted on a catheter shaft so as to be formed into an inflatable balloon comprising the sleeve having a first end, a second end, and a middle section; wherein **prior to being formed into the balloon by mounting on the catheter shaft at least one of the ends is non-distensible while the middle section of the sleeve is distensible.**

Chisum on Patents, Section 8.05, describes a product-by-process claim as one in which the product is defined at least in part in terms of the method or process by which it is made. The construction of claim 24, and specifically, the wherein clause stating "prior to being formed into the balloon by mounting on the catheter shaft" suggests that claim 24 must be considered and interpreted according to the guidelines for product-by-process claims.

Accordingly, case law has already defined the Guidelines for interpretation of product-by-process claims. The Court in *In re Thorpe* expressly concluded, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a

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product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process”.¹ Accordingly, with respect to claim 24, it is totally irrelevant that at least one of the ends of the sleeve is non-distensible prior to being formed into the balloon since the patentability of a product-by-process claim does not depend on the method of production, but rather in the structural characteristics of the final product.

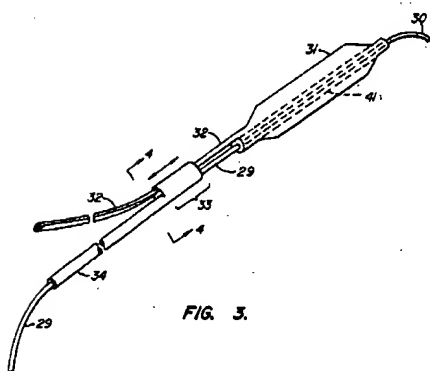
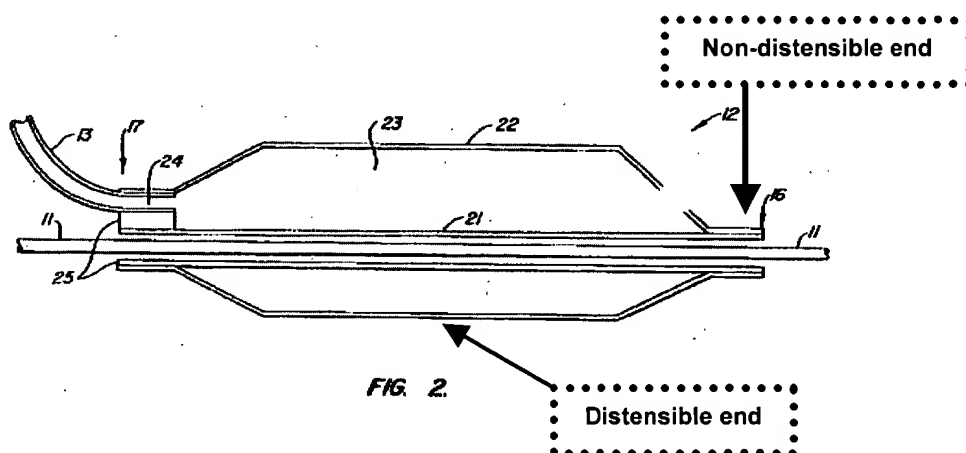
In this particular case, according to the preamble of claim 24, the final product is a balloon catheter since the preamble recites essential structure that is necessary to give life, meaning and vitality to the claim.² Consequentially, for the purposes of patentability, the claim must be interpreted as a balloon catheter having a sleeve forming a balloon wherein at least one of the ends is non-distensible while the middle section of the sleeve is distensible.

A careful review of Daneshvar and Kraus, et al., suggests that both patents disclose a “balloon catheter having a sleeve forming a balloon wherein at least one of the ends is non-distensible while the middle section of the sleeve is distensible”. Importantly, the Appellant agrees with this conclusion on page 4 of the Brief. In line 7, while discussing the teachings of the Daneshvar patent, the Appellant states, “any non-distensible ends that may be formed in this process will be created only after the sealed balloon is formed in conjunction with the center tubing” (emphasis added). Since the

¹ In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

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evaluation of claim 24 should be focused on the characteristics of the final product, the creation in Daneshvar of distensible ends after the formation of the sealed balloon is clearly a characteristic of the final product that can be utilized as evidence to evaluate the patentability of claim 24. Therefore, since Daneshvar discloses a balloon catheter having a sleeve forming a balloon wherein at least one of the ends is non-distensible while the middle section of the sleeve is distensible, it must be reasonable to conclude that Daneshvar anticipates the subject matter of claim 24.



U.S. Patent No. 5,718,680
Kraus, et al.
Figures 2 and 3

Concerning the merits of the rejection using Kraus, et al., figures 2 and 3 show a balloon catheter having a sleeve forming a balloon wherein at least one of the ends is

² Pitney Bowes, 51 USPQ2d at 1165-66; Kropa v. Robie, 88 USPQ 478, 480-481 (CCPA 1951).

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non-distensible (16) while the middle section of the sleeve is distensible (22). Based on the structural characteristics shown in the above figures, it would not be unreasonable to also conclude that the teachings of Kraus, et al., clearly demonstrate the conventionality of the subject matter disclosed by claim 24.

Finally, Appellant requested in the Brief that the grounds for rejection be considered against independent claim 24 alone. However, on pages 5 and 6, arguments pertaining to the patentability of the dependent claims are made. Accordingly, the examiner of record will briefly comment on the teachings of Crocker, et al., and Ravenscroft, et al.

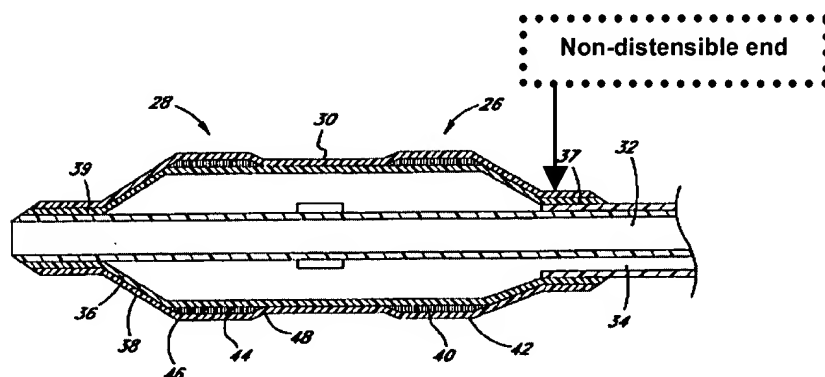


FIG. 2

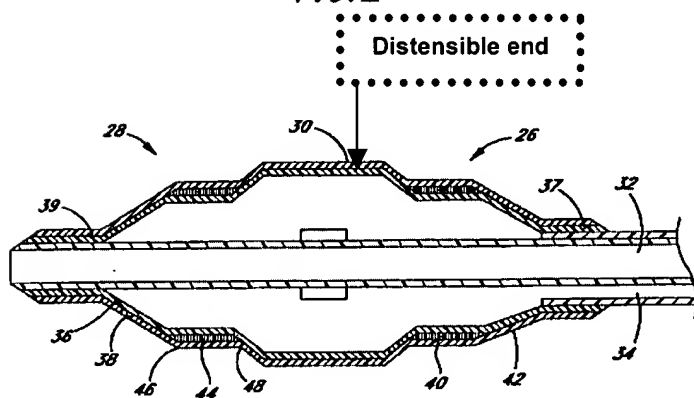


FIG. 3

U.S. Patent No. 5,843,116
Crocker, et al.
Figures 2 and 3

In figures 2 and 3, Crocker, et al., shows a balloon catheter having a sleeve forming a balloon wherein at least one of the ends is non-distensible (37,39) while the middle section of the sleeve is distensible (30). In view of these observations, Crocker, et al., anticipates the subject matter in claim 24. Concerning the merits of Ravenscroft, et al., it is respectfully noted that this patent also discloses a balloon catheter having a balloon with distensible and non-distensible sections. Therefore, since both patents disclose all the structural elements disclosed in claim 24, Appellant's arguments in the Brief should be considered non-persuasive. For the above reasons, it is believed that the rejections should be sustained.

Response to Arguments presented in the Reply Brief filed on April 13, 2005

The examiner notes for the record receipt of the Reply Brief filed on April 13, 2005. In this Brief, the Appellant introduced two arguments rebutting the examiner's analysis presented in the Examiner's Answer filed on February 9, 2005. These arguments state that (1) "the pending claims do not define a product-by-process and this misinterpretation of the claims should be rejected", and (2) "the examiner has interjected a new ground for rejection in his Answer. For the first time on pages 7-8 [of the Examiner's Answer] the examiner has rejected independent claim 24 as being anticipated by U.S. Patent 5,843,116 to Crocker et al."

In response to the first argument, the issue of whether claim 24 is or is not a product-by-process claim is a matter for the Board of Appeals to decide in due course. The examiner has carefully reviewed the arguments presented by the Appellant;

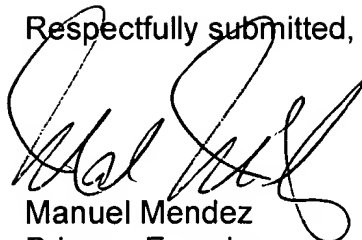
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however, it respectfully maintains his position that claim 24 is a product-by-process claim as explained in detailed in the Examiner's Answer filed on February 9, 2005.

In relation to the second argument, the examiner disagrees with the allegation that the Examiner's Answer included a new ground for rejection. On page 2 of the Appeal Brief, the section titled "Grouping of Claims" clearly states: "in order to make the appeal process as efficient as possible, applicants request that the grounds for rejection be considered against independent claim 24 alone". However, on pages 5 and 6 of the Appeal Brief the Appellant discusses the merits of Crocker et al., and Daneshvar with respect to the dependent claims, and concludes that "claim 24 of the present application is not anticipated under 35 U.S.C. Section 102(b) by either the Daneshvar or Kraus et al. patents or any of the other references of record".

Since the Appellant expanded the scope of the Brief by discussing the merits of the rejections of the dependent claims, and furthermore, the merits of the rejection of claim 24 under Section 102(b) using "any of the references of record", any explanations and arguments offered by the examiner in response to the allegations presented in the Brief, should not be considered a new grounds for rejection. Importantly, the examiner is required to provide comments about each and every argument presented by the Appellant. Since the Appellant "opened the gates" by expanding the scope of the Brief beyond the merits of the rejections of claim 24, the examiner is justified to rebut appellant's arguments, and consequently, said arguments should not be considered new grounds for rejection. For the above reasons, it is believed that the rejections should be sustained.

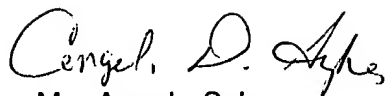
Respectfully submitted,



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September 22, 2005

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